Centers for Medicare & Medicaid Services, HHS  

§ 482.21 Condition of participation: Quality assessment and performance improvement program.

The hospital must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital’s governing body must ensure that the program reflects the complexity of the hospital’s organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.

(a) Standard: Program scope. (1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and identify and reduce medical errors.

(2) The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service and operations.

(b) Standard: Program data. (1) The program must incorporate quality indicator data including patient care data, and other relevant data, for example, information submitted to, or received from, the hospital’s Quality Improvement Organization.

(2) The hospital must use the data collected to—

(i) Monitor the effectiveness and safety of services and quality of care; and

(ii) Identify opportunities for improvement and changes that will lead to improvement.

(3) The frequency and detail of data collection must be specified by the hospital’s governing body.

(c) Standard: Program activities. (1) The hospital must set priorities for its performance improvement activities that—

(i) Focus on high-risk, high-volume, or problem-prone areas;

(ii) Consider the incidence, prevalence, and severity of problems in those areas; and

(iii) Affect health outcomes, patient safety, and quality of care.

(2) Performance improvement activities must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital.

(3) The hospital must take actions aimed at performance improvement and, after implementing those actions, the hospital must measure its success, and track performance to ensure that improvements are sustained.

(d) Standard: Performance improvement projects. As part of its quality assessment and performance improvement program, the hospital must conduct performance improvement projects.

(1) The number and scope of distinct improvement projects conducted annually must be proportional to the scope and complexity of the hospital’s services and operations.

(2) A hospital may, as one of its projects, develop and implement an information technology system explicitly designed to improve patient safety and quality of care. This project, in its initial stage of development, does not...
need to demonstrate measurable improvement in indicators related to health outcomes.

(3) The hospital must document what quality improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

(4) A hospital is not required to participate in a QIO cooperative project, but its own projects are required to be of comparable effort.

(e) Standard: Executive responsibilities.

The hospital’s governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:

(1) That an ongoing program for quality improvement and patient safety, including the reduction of medical errors, is defined, implemented, and maintained.

(2) That the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety; and that all improvement actions are evaluated.

(3) That clear expectations for safety are established.

(4) That adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital’s performance and reducing risk to patients.

(5) That the determination of the number of distinct improvement projects is conducted annually.

[68 FR 3454, Jan. 24, 2003]

§ 482.22 Condition of participation: Medical staff.

The hospital must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital.

(a) Standard: Composition of the medical staff.

The medical staff must be composed of doctors of medicine or osteopathy and, in accordance with State law, may also be composed of other practitioners appointed by the governing body.

(1) The medical staff must periodically conduct appraisals of its members.

(2) The medical staff must examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates.

(3) When telemedicine services are furnished to the hospital’s patients through an agreement with a distant-site hospital, the governing body of the hospital whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (a)(2) of this section, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site hospital when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the hospital’s governing body ensures, through its written agreement with the distant-site hospital, that all of the following provisions are met:

(i) The distant-site hospital providing the telemedicine services is a Medicare-participating hospital.

(ii) The individual distant-site physician or practitioner is privileged at the distant-site hospital providing the telemedicine services, which provides a current list of the distant-site physician’s or practitioner’s privileges at the distant-site hospital.

(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the hospital whose patients are receiving the telemedicine services is located.

(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the hospital whose patients are receiving the telemedicine services, the hospital has evidence of an internal review of the distant-site physician’s or practitioner’s performance of these privileges and sends the distant-site hospital such performance information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner.
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(4) When telemedicine services are furnished to the hospital’s patients through an agreement with a distant-site telemedicine entity, the governing body of the hospital whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (a)(2) of this section, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site telemedicine entity when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the hospital’s governing body ensures, through its written agreement with the distant-site telemedicine entity, that the distant-site telemedicine entity furnishes services that, in accordance with § 482.12(e), permit the hospital to comply with all applicable conditions of participation for the contracted services. The hospital’s governing body must also ensure, through its written agreement with the distant-site telemedicine entity, that all of the following provisions are met:

(i) The distant-site telemedicine entity’s medical staff credentialing and privileging process and standards at least meet the standards at § 482.12(a)(1) through (a)(7) and § 482.22(a)(1) through (a)(2).

(ii) The individual distant-site physician or practitioner is privileged at the distant-site telemedicine entity that provides the telemedicine services, which provides the hospital with a current list of the distant-site physician’s or practitioner’s privileges at the distant-site telemedicine entity.

(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the hospital whose patients are receiving such telemedicine services is located.

(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the hospital whose patients are receiving the telemedicine services, the hospital has evidence of an internal review of the distant-site physician’s or practitioner’s performance of these privileges and sends the distant-site telemedicine entity such performance information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the hospital’s patients, and all complaints the hospital has received about the distant-site physician or practitioner.

(b) Standard: Medical staff organization and accountability. The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to patients.

(1) The medical staff must be organized in a manner approved by the governing body.

(2) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.

(3) The responsibility for organization and conduct of the medical staff must be assigned only to an individual doctor of medicine or osteopathy or, when permitted by State law of the State in which the hospital is located, a doctor of dental surgery or dental medicine.

(c) Standard: Medical staff bylaws. The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must:

(1) Be approved by the governing body.

(2) Include a statement of the duties and privileges of each category of medical staff (e.g., active, courtesy, etc.)

(3) Describe the organization of the medical staff.

(4) Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body.

(5) Include a requirement that—

(i) A medical history and physical examination be completed and documented for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination must be
completed and documented by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

(ii) An updated examination of the patient, including any changes in the patient’s condition, be completed and documented within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before admission or registration. The updated examination of the patient, including any changes in the patient’s condition, must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.

(6) Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges. For distant-site physicians and practitioners requesting privileges to furnish telemedicine services under an agreement with the hospital, the criteria for determining privileges and the procedure for applying the criteria are also subject to the requirements in §482.12(a)(8) and (a)(9), and §482.22(a)(3) and (a)(4).

(d) Standard: Autopsies. The medical staff should attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. The mechanism for documenting permission to perform an autopsy must be defined. There must be a system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed.


§482.23 Condition of participation: Nursing services.

The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse.

(a) Standard: Organization. The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.

(b) Standard: Staffing and delivery of care. The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.

(1) The hospital must provide 24-hour nursing services furnished or supervised by a registered nurse, and have a licensed practical nurse or registered nurse on duty at all times, except for rural hospitals that have in effect a 24-hour nursing waiver granted under §488.54(c) of this chapter.

(2) The nursing service must have a procedure to ensure that hospital nursing personnel for whom licensure is required have valid and current licensure.

(3) A registered nurse must supervise and evaluate the nursing care for each patient.

(4) The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient.

(5) A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient’s needs and the specialized qualifications and competence of the nursing staff available.

(6) Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing service.
(c) Standard: Preparation and administration of drugs. Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient’s care as specified under §482.12(c), and accepted standards of practice.

(1) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

(2) With the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered by physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders by hospital policy and in accordance with State law, and who is responsible for the care of the patient as specified under §482.12(c).

(i) If verbal orders are used, they are to be used infrequently.

(ii) When verbal orders are used, they must only be accepted by persons who are authorized to do so by hospital policy and procedures consistent with Federal and State law.

(3) Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures. If blood transfusions and intravenous medications are administered by personnel other than doctors of medicine or osteopathy, the personnel must have special training for this duty.

(4) There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

§482.24 Condition of participation: Medical record services.

The hospital must have a medical record service that has administrative responsibility for medical records. A medical record must be maintained for every individual evaluated or treated in the hospital.

(a) Standard: Organization and staffing. The organization of the medical record service must be appropriate to the scope and complexity of the services performed. The hospital must employ adequate personnel to ensure prompt completion, filing, and retrieval of records.

(b) Standard: Form and retention of record. The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.

(1) Medical records must be retained in their original or legally reproduced form for a period of at least 5 years.

(2) The hospital must have a system of coding and indexing medical records. The system must allow for timely retrieval by diagnosis and procedure, in order to support medical care evaluation studies.

(3) The hospital must have a procedure for ensuring the confidentiality of patient records. Information from or copies of records may be released only to authorized individuals, and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records must be released by the hospital only in accordance with Federal or State laws, court orders, or subpoenas.

(c) Standard: Content of record. The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient’s progress and response to medications and services.

(1) All patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures.
(i) All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner, except as noted in paragraph (c)(1)(ii) of this section.

(ii) For the 5 year period following January 26, 2007, all orders, including verbal orders, must be dated, timed, and authenticated by the ordering practitioner or another practitioner who is responsible for the care of the patient as specified under §482.12(c) and authorized to write orders by hospital policy in accordance with State law.

(iii) All verbal orders must be authenticated based upon Federal and State law. If there is no State law that designates a specific timeframe for the authentication of verbal orders, verbal orders must be authenticated within 48 hours.

(2) All records must document the following, as appropriate:

(i) Evidence of—

(A) A medical history and physical examination completed and documented no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services. The medical history and physical examination must be placed in the patient’s medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.

(B) An updated examination of the patient, including any changes in the patient’s condition, when the medical history and physical examination are completed within 30 days before admission or registration. Documentation of the updated examination must be placed in the patient’s medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.

(ii) Admitting diagnosis.

(iii) Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient.

(iv) Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia.

(v) Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.

(vi) All practitioners’ orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient’s condition.

(vii) Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow-up care.

(viii) Final diagnosis with completion of medical records within 30 days following discharge.

§482.25 Condition of participation: Pharmaceutical services.

The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital’s organized pharmaceutical service.

(a) Standard: Pharmacy management and administration. The pharmacy or drug storage area must be administered in accordance with accepted professional principles.

(1) A full-time, part-time, or consulting pharmacist must be responsible for developing, supervising, and coordinating all the activities of the pharmacy services.

(2) The pharmaceutical service must have an adequate number of personnel to ensure quality pharmaceutical services, including emergency services.

(3) Current and accurate records must be kept of the receipt and disposition of all scheduled drugs.

(b) Standard: Delivery of services. In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.

(1) All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws.
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(2)(i) All drugs and biologicals must be kept in a secure area, and locked when appropriate.
(ii) Drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area.
(iii) Only authorized personnel may have access to locked areas.

(3) Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.

(4) When a pharmacist is not available, drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and State law.

(5) Drugs and biologicals not specifically prescribed as to time or number of doses must automatically be stopped after a reasonable time that is predetermined by the medical staff.

(6) Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the hospital-wide quality assurance program.

(7) Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

§ 482.26 Condition of participation: Radiologic services.

The hospital must maintain, or have available, diagnostic radiologic services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.

(a) Standard: Radiologic services. The hospital must maintain, or have available, radiologic services according to needs of the patients.

(b) Standard: Safety for patients and personnel. The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.

(1) Proper safety precautions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.

(2) Periodic inspection of equipment must be made and hazards identified must be promptly corrected.

(3) Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.

(4) Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services.

(c) Standard: Personnel. (1) A qualified full-time, part-time, or consulting radiologist must supervise the ionizing radiology services and must interpret only those radiologic tests that are determined by the medical staff to require a radiologist’s specialized knowledge. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.

(2) Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.

(d) Standard: Records. Records of radiologic services must be maintained.

(1) The radiologist or other practitioner who performs radiology services must sign reports of his or her interpretations.

(2) The hospital must maintain the following for at least 5 years:

(i) Copies of reports and printouts.

(ii) Films, scans, and other image records, as appropriate.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986; 71 FR 68694, Nov. 27, 2006]
§ 482.27  Condition of participation: Laboratory services.

The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients. The hospital must ensure that all laboratory services provided to its patients are performed in a facility certified in accordance with part 493 of this chapter.

(a) Standard: Adequacy of laboratory services. The hospital must have laboratory services available, either directly or through a contractual agreement with a certified laboratory, that meets requirements of part 493 of this chapter.

(1) Emergency laboratory services must be available 24 hours a day.

(2) A written description of services provided must be available to the medical staff.

(3) The laboratory must make provision for proper receipt and reporting of tissue specimens.

(4) The medical staff and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.

(b) Standard: Potentially infectious blood and blood components—(1) Potentially human immunodeficiency virus (HIV) infectious blood and blood components. Potentially HIV infectious blood and blood components are prior collections from a donor—

(i) Who tested negative at the time of donation but tests reactive for evidence of HIV infection on a later donation;

(ii) Who tests positive on the supplemental (additional, more specific) test for HIV or HCV, as relevant, or other follow-up testing required by FDA; and

(iii) For whom the timing of seroconversion cannot be precisely estimated.

(2) Potentially hepatitis C virus (HCV) infectious blood and blood components. Potentially HCV infectious blood and blood components are the blood and blood components identified in 21 CFR 610.47.

(3) Services furnished by an outside blood collecting establishment. If a hospital regularly uses the services of an outside blood collecting establishment, it must have an agreement with the blood collecting establishment that governs the procurement, transfer, and availability of blood and blood components. The agreement must require that the blood collecting establishment notify the hospital—

(i) Within 3 calendar days if the blood collecting establishment supplied blood and blood components collected from a donor who tested negative at the time of donation but tests reactive for evidence of HIV or HCV infection on a later donation or who is determined to be at increased risk for transmitting HIV or HCV infection;

(ii) Within 45 days of the test, of the results of the supplemental (additional, more specific) test for HIV or HCV, as relevant, or other follow-up testing required by FDA; and

(iii) Within 3 calendar days after the blood collecting establishment supplied blood and blood components collected from an infectious donor, whenever records are available, as set forth at 21 CFR 610.48(b)(3).

(4) Quarantine and disposition of blood and blood components pending completion of testing. If the blood collecting establishment (either internal or under an agreement) notifies the hospital of the reactive HIV or HCV screening test results, the hospital must determine the disposition of the blood or blood product and quarantine all blood and blood components from previous donations in inventory.

(i) If the blood collecting establishment notifies the hospital that the result of the supplemental (additional, more specific) test or other follow-up testing required by FDA is negative, absent other informative test results, the hospital may release the blood and blood components from quarantine.

(ii) If the blood collecting establishment notifies the hospital that the result of the supplemental, (additional, more specific) test or other follow-up testing required by FDA is positive, the hospital must—

(A) Dispose of the blood and blood components; and

(B) Notify the transfusion recipients as set forth in paragraph (b)(6) of this section.
(iii) If the blood collecting establishment notifies the hospital that the result of the supplemental, (additional, more specific) test or other follow-up testing required by FDA is indeterminate, the hospital must destroy or label prior collections of blood or blood components held in quarantine as set forth at 21 CFR 610.46(b)(2), 610.47(b)(2), and 610.48(c)(2).

(5) Recordkeeping by the hospital. The hospital must maintain—

(i) Records of the source and disposition of all units of blood and blood components for at least 10 years from the date of disposition in a manner that permits prompt retrieval; and

(ii) A fully funded plan to transfer these records to another hospital or other entity if such hospital ceases operation for any reason.

(6) Patient notification. If the hospital has administered potentially HIV or HCV infectious blood or blood components (either directly through its own blood collecting establishment or under an agreement) or released such blood or blood components to another entity or individual, the hospital must take the following actions:

(i) Make reasonable attempts to notify the patient, or to notify the attending physician or the physician who ordered the blood or blood component and ask the physician to notify the patient, or other individual as permitted under paragraph (b)(10) of this section, that potentially HIV or HCV infectious blood and blood components were transfused to the patient and that there may be a need for HIV or HCV testing and counseling.

(ii) If the physician is unavailable or declines to make the notification, make reasonable attempts to give this notification to the patient, legal guardian, or relative.

(iii) Document in the patient’s medical record the notification or attempts to give the required notification.

(7) Timeframe for notification—(i) For donors tested on or after February 20, 2008. For notifications resulting from donors tested on or after February 20, 2008 as set forth at 21 CFR 610.46 and 61 CFR 610.47 the notification begins when the blood collecting establishment notifies the hospital that it received potentially HIV or HCV infectious blood and blood components. The hospital must make reasonable attempts to give notification over a period of 12 weeks unless—

(A) The patient is located and notified; or

(B) The hospital is unable to locate the patient and documents in the patient’s medical record the extenuating circumstances beyond the hospital’s control that caused the notification timeframe to exceed 12 weeks.

(ii) For donors tested before February 20, 2008. For notifications resulting from donors tested before February 20, 2008 as set forth at 21 CFR 610.46(b) and (c), the notification effort begins when the blood collecting establishment notifies the hospital that it received potentially HCV infectious blood and blood components. The hospital must make reasonable attempts to give notification and must complete the actions within 1 year of the date on which the hospital received notification from the outside blood collecting establishment.

(8) Content of notification. The notification must include the following information:

(i) A basic explanation of the need for HIV or HCV testing and counseling;

(ii) Enough oral or written information so that an informed decision can be made about whether to obtain HIV or HCV testing and counseling; and

(iii) A list of programs or places where the person can obtain HIV or HCV testing and counseling, including any requirements or restrictions the program may impose.

(9) Policies and procedures. The hospital must establish policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for the confidentiality of medical records and other patient information.

(10) Notification to legal representative or relative. If the patient has been adjudged incompetent by a State court, the physician or hospital must notify a legal representative designated in accordance with State law. If the patient is competent, but State law permits a legal representative or relative to receive the information on the patient’s behalf, the physician or hospital must notify the patient or his or her legal
representative or relative. For possible HIV infectious transfusion recipients that are deceased, the physician or hospital must inform the deceased patient’s legal representative or relative. If the patient is a minor, the parents or legal guardian must be notified.

(11) Applicability. HCV notification requirements resulting from donors tested before February 20, 2008 as set forth at 21 CFR 610.48 will expire on August 24, 2015.

(c) General blood safety issues. For lookback activities only related to new blood safety issues that are identified after August 24, 2007, hospitals must comply with FDA regulations as they pertain to blood safety issues in the following areas:

(1) Appropriate testing and quarantining of infectious blood and blood components.

(2) Notification and counseling of recipients that may have received infectious blood and blood components.

§ 482.28 Condition of participation: Food and dietetic services.

The hospital must have organized dietary services that are directed and staffed by adequate qualified personnel. However, a hospital that has a contract with an outside food management company may be found to meet this Condition of participation if the company has a dietitian who serves the hospital on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standards specified in this section and provides for constant liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment.

(a) Standard: Organization. (1) The hospital must have a full-time employee who—

(i) Serves as director of the food and dietetic service;

(ii) Is responsible for the daily management of the dietary services; and

(iii) Is qualified by experience or training.

(2) There must be a qualified dietitian, full-time, part-time, or on a consultant basis.

(3) There must be administrative and technical personnel competent in their respective duties.

(b) Standard: Diets. Menus must meet the needs of the patients.

(1) Therapeutic diets must be prescribed by the practitioner or practitioners responsible for the care of the patients.

(2) Nutritional needs must be met in accordance with recognized dietary practices and in accordance with orders of the practitioner or practitioners responsible for the care of the patients.

(3) A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.

§ 482.30 Condition of participation: Utilization review.

The hospital must have in effect a utilization review (UR) plan that provides for review of services furnished by the institution and by members of the medical staff to patients entitled to benefits under the Medicare and Medicaid programs.

(a) Applicability. The provisions of this section apply except in either of the following circumstances:

(1) A Utilization and Quality Control Quality Improvement Organization (QIO) has assumed binding review for the hospital.

(2) CMS has determined that the UR procedures established by the State under title XIX of the Act are superior to the procedures required in this section, and has required hospitals in that State to meet the UR plan requirements under §§456.50 through 456.245 of this chapter.

(b) Standard: Composition of utilization review committee. A UR committee consisting of two or more practitioners must carry out the UR function. At least two of the members of the committee must be doctors of medicine or osteopathy. The other members may be any of the other types of practitioners specified in §482.12(c)(1).

(1) Except as specified in paragraphs (b) (2) and (3) of this section, the UR committee must be one of the following:

(i) A staff committee of the institution;
(ii) A group outside the institution—
(A) Established by the local medical society and some or all of the hospitals in the locality; or
(B) Established in a manner approved by CMS.
(2) If, because of the small size of the institution, it is impracticable to have a properly functioning staff committee, the UR committee must be established as specified in paragraph (b)(1)(ii) of this section.
(3) The committee's or group's reviews may not be conducted by any individual who—
(i) Has a direct financial interest (for example, an ownership interest) in that hospital; or
(ii) Was professionally involved in the care of the patient whose case is being reviewed.
(c) Standard: Scope and frequency of review. (1) The UR plan must provide for review for Medicare and Medicaid patients with respect to the medical necessity of—
(i) Admissions to the institution;
(ii) The duration of stays; and
(iii) Professional services furnished, including drugs and biologicals.
(2) Review of admissions may be performed before, at, or after hospital admission.
(3) Except as specified in paragraph (e) of this section, reviews may be conducted on a sample basis.
(4) Hospitals that are paid for inpatient hospital services under the prospective payment system set forth in Part 412 of this chapter must conduct review of duration of stays and review of professional services as follows:
(i) For duration of stays, these hospitals need review only cases that they reasonably assume to be outlier cases based on extended length of stay, as described in §412.80(a)(1)(i) of this chapter; and
(ii) For professional services, these hospitals need review only cases that they reasonably assume to be outlier cases based on extraordinarily high costs, as described in §412.80(a)(1)(ii) of this chapter.
(d) Standard: Determination regarding admissions or continued stays. (1) The determination that an admission or continued stay is not medically necessary—
(i) May be made by one member of the UR committee if the practitioner or practitioners responsible for the care of the patient, as specified of §482.12(c), concur with the determination or fail to present their views when afforded the opportunity; and
(ii) Must be made by at least two members of the UR committee in all other cases.
(2) Before making a determination that an admission or continued stay is not medically necessary, the UR committee must consult the practitioner or practitioners responsible for the care of the patient, as specified in §482.12(c), and afford the practitioner or practitioners the opportunity to present their views.
(3) If the committee decides that admission to or continued stay in the hospital is not medically necessary, written notification must be given, no later than 2 days after the determination, to the hospital, the patient, and the practitioner or practitioners responsible for the care of the patient, as specified in §482.12(c);
(e) Standard: Extended stay review. (1) In hospitals that are not paid under the prospective payment system, the UR committee must make a periodic review, as specified in the UR plan, of each current inpatient receiving hospital services during a continuous period of extended duration. The scheduling of the periodic reviews may—
(i) Be the same for all cases; or
(ii) Differ for different classes of cases.
(2) In hospitals paid under the prospective payment system, the UR committee must review all cases reasonably assumed by the hospital to be outlier cases because the extended length of stay exceeds the threshold criteria for the diagnosis, as described in §412.80(a)(1)(i). The hospital is not required to review an extended stay that does not exceed the outlier threshold for the diagnosis.
(3) The UR committee must make the periodic review no later than 7 days after the day required in the UR plan.
(f) Standard: Review of professional services. The committee must review
§ 482.41 Condition of participation: Physical environment.

The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community.

(a) Standard: Buildings. The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured:

1. There must be emergency power and lighting in at least the operating, recovery, intensive care, and emergency rooms, and stairwells. In all other areas not serviced by the emergency supply source, battery lamps and flashlights must be available.

2. There must be facilities for emergency gas and water supply.

(b) Standard: Life safety from fire. (1) Except as otherwise provided in this section—

   (i) The hospital must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

   (ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to hospitals.

   (2) After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of the patients.

   (3) The provisions of the Life Safety Code do not apply in a State where CMS finds that a fire and safety code imposed by State law adequately protects patients in hospitals.

   (4) Beginning March 13, 2006, a hospital must be in compliance with Chapter 19.2.9, Emergency Lighting.

   (5) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to hospitals.

   (6) The hospital must have procedures for the proper routine storage and prompt disposal of trash.

   (7) The hospital must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel and guests; evacuation; and cooperation with fire fighting authorities.

   (8) The hospital must maintain written evidence of regular inspection and approval by State or local fire control agencies.

   (9) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a hospital may install alcohol-based hand rub dispensers in its facility if—

      (i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

      (ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

      (iii) The dispensers are installed in a manner that adequately protects against inappropriate access;

      (iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment...
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00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269; and

(v) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

(c) Standard: Facilities. The hospital must maintain adequate facilities for its services.

(1) Diagnostic and therapeutic facilities must be located for the safety of patients.

(2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

(3) The extent and complexity of facilities must be determined by the services offered.

(4) There must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.


§ 482.44 Condition of participation: Infection control.

The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.

(a) Standard: Organization and policies. A person or persons must be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases.

(1) The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.

(2) The infection control officer or officers must maintain a log of incidents related to infections and communicable diseases.

(b) Standard: Responsibilities of chief executive officer, medical staff, and director of nursing services. The chief executive officer, the medical staff, and the director of nursing services must—

(1) Ensure that the hospital-wide quality assurance program and training programs address problems identified by the infection control officer or officers; and

(2) Be responsible for the implementation of successful corrective action plans in affected problem areas.

§ 482.43 Condition of participation: Discharge planning.

The hospital must have in effect a discharge planning process that applies to all patients. The hospital’s policies and procedures must be specified in writing.

(a) Standard: Identification of patients in need of discharge planning. The hospital must identify at an early stage of hospitalization all patients who are likely to suffer adverse health consequences upon discharge if there is no adequate discharge planning.

(b) Standard: Discharge planning evaluation. (1) The hospital must provide a discharge planning evaluation to the patients identified in paragraph (a) of this section, and to other patients upon the patient’s request, the request of a person acting on the patient’s behalf, or the request of the physician.

(2) A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of, the evaluation.

(3) The discharge planning evaluation must include an evaluation of the likelihood of a patient needing post-hospital services and of the availability of the services.

(4) The discharge planning evaluation must include an evaluation of the likelihood of a patient’s capacity for self-care or of the possibility of the patient being cared for in the environment.
§ 482.45 Condition of participation: Organ, tissue, and eye procurement.

(a) Standard: Organ procurement responsibilities. The hospital must have and implement written protocols that:

(1) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the hospital. The OPO determines medical suitability for organ
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§ 482.51 Condition of participation: Surgical services.

(a) Standard: Organization and staffing. The organization of the surgical services must be appropriate to the scope of the services offered.

(1) The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.

(2) Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as “scrub nurses” under the supervision of a registered nurse.

(3) Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the supervision of a qualified registered nurse.